terminus from left to right is toxin moiety,VL,L,VH,L,VL,L,VH, wherein the toxin moiety comprises a truncation mutation, L is a (G4S)3 linker, and VL and VH are the variable light and heavy domains of the anti-CD3 antibody UCHT1.--

REMARKS

Claims 26, 27, and 30-43 are pending in the application and claims 27 and 30-42 have been withdrawn from consideration as being drawn to a non-elected invention. Claim 26 and 43 are under consideration.

Claim 26 is amended herein to delete the phrase "and H is the γIgG hinge" because the claim was previously amended to delete the constructs having an H designation. The clause related to the H region is no longer necessary. Support for this amendment is present in claim 26 as originally filed, and no new matter is believed to be added. The amendment is merely to avoid the presence of an unnecessary clause and is not made for reasons related to patentability. A copy of the marked-up claim is attached as Appendix A.

Claims 26 and 43 have been rejected. Applicants respectfully traverse the rejection of claims 26 and 43.

Applicants note that the traversal of the restriction of the claims into three Groups has been considered but not found persuasive. However Applicants maintain their traversal because the Applicants believe the PTO has not met their burden in showing that the claims lack a common inventive concept.

A. Rejection Under 35 U.S.C. § 102

The Office Action dated May 22, 2001, rejected claims 26 and 43, under 35 U.S.C. § 102 for allegedly being anticipated by WO96/32137.

The PTO asserts that WO96/32137 teaches an anti-T cell immunotoxin comprising an scUCHT-DT390 immunotoxin where the immunotoxin further comprises μCH2,μCH3,VL,VH, γIgG hinge H, where L is a $(G4S)_3$.

Claims 26 and 43, however, are drawn to immunotoxin sequences wherein the sequence from the amino terminus from left to right is toxin moiety, VL,L,VH,L,VL,L,VH, wherein the toxin moiety comprises a truncation mutation, L is a $(G_4S)_3$ (SEQ ID NO:16) linker, and VL and VH are the variable light and heavy domains of the anti-CD3 antibody UCHT1. Thus, claims 26 and 43 require at least two VL units, two VH units, and three linkers. WO96/32137 does not recite such a molecule. The section of WO96/32137 discussed by the Examiner, discusses a molecule comprising a VL-L-VH construct, not a VL-L-VH-L-VL-L-VH construct. Thus, WO96/32137 cannot anticipate claims 26 and 43 because each and every element of the claimed subject matter is not present in WO96/32137.

The Office Action dated May 22, 2001, also rejected claims 26 and 43, under 35 U.S.C. § 102 for allegedly being anticipated by Thompson et al., *J. Biol. Chem.* 270:28037-28041 (1995). The PTO asserts that Thompson et al. teaches a scUCTH-DT390 immunotoxin having μCH2, μCH3, VL, VH, γIgG hinge H, and L regions. Thompson et al. does not disclose an immunotoxin having the sequence from the amino terminus from left to right as toxin moiety, VL,L,VH,L,VL,L,VH, wherein the toxin moiety comprises a truncation mutation, L is a $(G_4S)_3$ (SEQ ID NO:16) linker, and VL and VH are the variable light and heavy domains of the anti-CD3 antibody UCHT1. Thus, Thomson et al. cannot anticipate the claimed subject matter because each and every element of claims 26 and 43 is not disclosed in Thompson et al. Applicants respectfully traverse this rejection and request allowance of the pending claims.

B. Reference not considered by the Examiner

The Examiner has indicated that the following references, Coffin, J.C. Science (1992) 255:411-413, January; Oluwole et al. *Transplantation Immunity and GVH Disease II* Abstract 2723 *FASEB* (1992); and Oluwole et al. *Transplantation Proceedings* (1993) 25(1):299-300, listed on the PTO-1449 filed on January 13, 2000, have not been considered because copies of these references were inadvertently not provided. Enclosed with this Response are copies of these references and Applicants respectfully request consideration of these references.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

No additional fees are believed due, however, the Commissioner is hereby authorized to change any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Tina Williams McKeon
Registration No. 43,791

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
404/688-0770

I hereby certify that this correspondence and anything indicated as included with this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee, Assistant Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Tina Williams McKeon — August 9, 2001
Date

Version with Marked-up Claims

26. An anti-T cell immunotoxin fusion protein comprising a diphtheria toxin moiety and a targeting moiety, wherein the sequence from the amino terminus from left to right is toxin moiety,VL,L,VH,L,VL,L,VH, wherein the toxin moiety comprises a truncation mutation, L is a (G4S)3 linker, and VL and VH are the variable light and heavy domains of the anti-CD3 antibody UCHT1[, and H is the γIgG hinge].